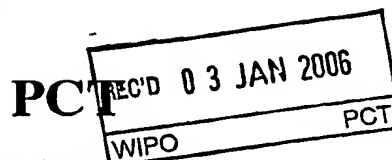


# PATENT COOPERATION TREATY

From the  
INTERNATIONAL SEARCHING AUTHORITY

To:  
MERCK & CO., INC.  
126 EAST LINCOLN AVENUE  
RAHWAY, NJ 07065-0907



## WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY

(PCT Rule 43bis.1)

To: MERCK & CO., INC. 126 EAST LINCOLN AVENUE RAHWAY, NJ 07065-0907		Date of mailing (day/month/year) <b>27 DEC 2005</b>
Applicant's or agent's file reference  PCT 21668Y		FOR FURTHER ACTION See paragraph 2 below
International application No.  PCT/US05/09562	International filing date (day/month/year)  22 March 2005 (22.03.2005)	Priority date (day/month/year)  26 March 2004 (26.03.2004)
International Patent Classification (IPC) or both national classification and IPC  IPC(7): A61K 31/445 and US Cl.: 514/319, 326, 397		
Applicant  MERCK & CO., INC.		

**1. This opinion contains indications relating to the following items:**

- ☒ Box No. I      Basis of the opinion
- ☐ Box No. II      Priority
- ☐ Box No. III      Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- ☐ Box No. IV      Lack of unity of invention
- ☒ Box No. V      Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- ☐ Box No. VI      Certain documents cited
- ☐ Box No. VII      Certain defects in the international application
- ☐ Box No. VIII      Certain observations on the international application

**2. FURTHER ACTION**

If a demand for international preliminary examination is made, this opinion will be considered to be a written opinion of the International Preliminary Examining Authority ("IPEA") except that this does not apply where the applicant chooses an Authority other than this one to be the IPEA and the chosen IPEA has notified the International Bureau under Rule 66.1bis(b) that written opinions of this International Searching Authority will not be so considered.

If this opinion is, as provided above, considered to be a written opinion of the IPEA, the applicant is invited to submit to the IPEA a written reply together, where appropriate, with amendments, before the expiration of 3 months from the date of mailing of Form PCT/ISA/220 or before the expiration of 22 months from the priority date, whichever expires later.

For further options, see Form PCT/ISA/220.

**3. For further details, see notes to Form PCT/ISA/220.**

Name and mailing address of the ISA/ US Mail Stop PCT, Attn: ISA/US Commissioner for Patents P.O. Box 1450 Alexandria, Virginia 22313-1450 Facsimile No. (571) 273-3201	Date of completion of this opinion  03 December 2005 (03.12.2005)	Authorized officer  Sreenivasan Padmanabhan <i>F. Roberts for</i> Telephone No. (571) 272-1600
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Form PCT/ISA/237 (cover sheet) (April 2005)

WRITTEN OPINION OF THE  
INTERNATIONAL SEARCHING AUTHORITY

International application No.

PCT/US05/09562

Box No. I Basis of this opinion

1. With regard to the language, this opinion has been established on the basis of:

- ☒ the international application in the language in which it was filed  
☐ a translation of the international application into \_\_\_\_\_, which is the language of a translation furnished for the purposes of international search (Rules 12.3(a) and 23.1(b)).

2. With regard to any nucleotide and/or amino acid sequence disclosed in the international application and necessary to the claimed invention, this opinion has been established on the basis of:

a. type of material

- ☐ a sequence listing  
☐ table(s) related to the sequence listing

b. format of material

- ☐ on paper  
☐ in electronic form

c. time of filing/furnishing

- ☐ contained in the international application as filed.  
☐ filed together with the international application in electronic form.  
☐ furnished subsequently to this Authority for the purposes of search.

3. ☐ In addition, in the case that more than one version or copy of a sequence listing and/or table(s) relating thereto has been filed or furnished, the required statements that the information in the subsequent or additional copies is identical to that in the application as filed or does not go beyond the application as filed, as appropriate, were furnished.

4. Additional comments:

WRITTEN OPINION OF THE  
INTERNATIONAL SEARCHING AUTHORITY

International application No.  
PCT/US05/09562

Box No. V Reasoned statement under Rule 43 bis.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)

Claims NONE YES  
Claims 1-15 NO

Inventive step (IS)

Claims NONE YES  
Claims 1-15 NO

Industrial applicability (IA)

Claims 1-15 YES  
Claims NONE NO

2. Citations and explanations:

Claims 1-15 lack novelty under PCT Article 33(2) as being anticipated by DURANT et al. (US 5,486,526 A1). DURANT et al. teaches the histamine H3-receptor antagonist useful for the treatment of a subject suffering from Parkinson's diseases, tardive dyskinesia and hyperkinesias. (abstract, column 9, lines 11-48, particularly, line 40-45).

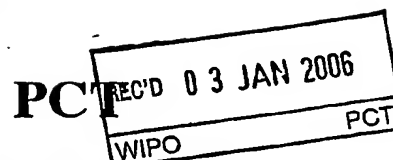
Claims 1-15 lack an inventive step under PCT Article 33(3) as being obvious over DURANT et al. (US 5,486,526 A1). DURANT et al. teaches the histamine H3-receptor antagonist useful for the treatment of a subject suffering from Parkinson's diseases, tardive dyskinesia and hyperkinesias. (abstract, column 9, lines 11-48, particularly, line 40-45). Applicant's limitation of the tremor associated with Parkinson's disease is obviously eliminated upon treatment of the same disorder, i.e. Parkinson's disease, tardive dyskinesia and hyperkinesias.

Claims 1-15 meet the criteria set out in PCT Article 33(4), because the method for treating, controlling, ameliorating or reducing the risk of a movement disorder in a patient in need thereof that comprises administering to the patient a therapeutically effective amount of a histamine H3-inverse agonist or a histamine H3 antagonist, or a pharmaceutically acceptable salt thereof has an industrial applicability in pharmaceutical art.

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4. Additional comments:

WRITTEN OPINION OF THE  
INTERNATIONAL SEARCHING AUTHORITY

International application No.  
PCT/US05/09562

Box No. V Reasoned statement under Rule 43 bis.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Claims <u>NONE</u>	YES
	Claims <u>1-15</u>	NO
Inventive step (IS)	Claims <u>NONE</u>	YES
	Claims <u>1-15</u>	NO
Industrial applicability (IA)	Claims <u>1-15</u>	YES
	Claims <u>NONE</u>	NO

2. Citations and explanations:

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